

TRUST IBUPROFEN PLUS CODEINE

Ibuprofen 200mg and Codeine phosphate hemihydrate 12.8mg

Consumer Medicine Information

WARNINGS

Limitations of use

Because of the risks associated with the use of opioids, TRUST IBUPROFEN PLUS CODEINE should only be used in patients for whom other treatment options, including non-opioid analgesics, are ineffective, not tolerated or otherwise inadequate to provide appropriate management of pain. Hazardous and harmful use

TRUST IBUPROFEN PLUS CODEINE poses risks of hazardous and harmful use which can lead to overdose and death. Assess the patient's risk of hazardous and harmful use before prescribing and monitor the patient regularly during treatment

Life threatening respiratory depression

Serious, life-threatening or fatal respiratory depression may occur with the use of TRUST IBUPROFEN PLUS CODEINE. Be aware of situations which increase the risk of respiratory depression, modify dosing in patients at risk and monitor patients closely, especially on initiation or following a dose increase

Concomitant use of benzodiazepines and other central nervous system (CNS) depressants, including alcohol

Concomitant use of opioids with benzodiazepines, gabapentinoids, antihistamines, tricyclic antidepressants, antipsychotics, cannabis or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Limit dosages and durations to the minimum required; and monitor patients for signs and symptoms of respiratory depression and sedation. Caution patients not to drink alcohol while taking TRUST IBUPROFEN PLUS CODEINE.

What is in this Leaflet?

This leaflet answers some common questions about Trust Ibuprofen Plus Codeine. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Trust Ibuprofen Plus Codeine against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine.

You may need to read it again

What Trust Ibuprofen Plus Codeine is used for

Trust Ibuprofen Plus Codeine tablets contain the active ingredients Ibuprofen and Codeine phosphate. Ibuprofen belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines work by relieving pain and/or inflammation (swelling, redness, soreness) and fever. Codeine is an opioid analgesic that works in the brain and spinal cord to relieve pain.

Trust Ibuprofen Plus Codeine provides temporary relief of acute moderate pain and inflammation in patients over the age of 12 years.

After taking codeine, the body changes codeine into the active morphine by a special liver enzyme. However, about 8% of people may experience less pain relief compared to others, as their bodies do not change codeine to morphine as well as others.

Do not give Trust Ibuprofen Plus Codeine to children under the age of 12 years.

Ask your doctor if you have any questions about this medicine.

Your doctor may have given it for another reason.

Before You Take Trust Ibuprofen Plus Codeine

When you must not take it

Do not take Trust Ibuprofen Plus Codeine if

1. you have an allergy to:
 - Ibuprofen, codeine or other opioids, or any of the ingredients listed at the end of this leaflet.

- any medicine containing ibuprofen, aspirin or other NSAIDs
- Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID. If you are not sure if you are taking any of these medicines, ask your pharmacist.
- Symptoms of an allergic reaction to these medicines may include:
- asthma, wheezing or shortness of breath.
 - swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.
 - hives, itching or skin rash.
 - fainting.
- If you are allergic to aspirin or NSAIDs and take Trust Ibuprofen Plus Codeine these symptoms may be severe.**
2. you are in the last three months of pregnancy or are breastfeeding
- Trust Ibuprofen Plus Codeine should not be taken during pregnancy except during the first 6 months of pregnancy. All NSAIDs should not be taken during the last three months of pregnancy.
3. you are vomiting blood or material that looks like coffee grounds
 4. you are bleeding from the rectum (back passage), have black sticky bowel motions (stool) or bloody diarrhoea
 5. you have peptic ulcer (i.e. stomach or duodenal ulcer), or have had one before.
 6. you are using other NSAIDs
 7. you have chronic constipation or shallow breathing, or severe diarrhoea.
 8. You consume regular and heavy amounts of alcohol.
 9. You are a CYP2D6 ultra-rapid metaboliser.

Do not take Trust Ibuprofen Plus Codeine if the packaging is torn or shows signs of tampering.

Do not take Trust Ibuprofen Plus Codeine if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start taking Trust Ibuprofen Plus Codeine, contact your pharmacist or doctor.

Do not give Trust Ibuprofen Plus Codeine to children under 12 years or to those aged 12 - 18 years in whom respiratory function may be compromised.

Before you start to take it

Tell your doctor if

1. you have allergies to:
 - any other medicines including aspirin, or other NSAID medicines.
 - any other substances, such as foods, preservatives or dyes.
 2. you are pregnant or intend to become pregnant
- Trust Ibuprofen Plus Codeine is not recommended during the last 3 months of pregnancy. Your doctor will decide if you should take Trust Ibuprofen Plus Codeine during the first 6 months of pregnancy.
3. you are breast-feeding or plan to breast-feed
- Trust Ibuprofen Plus Codeine should not be taken while breastfeeding except on your doctor's advice. Codeine passes into the breast milk. If there is a need to consider Trust Ibuprofen Plus Codeine while you are breast-feeding, your pharmacist or doctor will discuss with you the benefits and risks of using it.
4. you have or have had any of the following medical conditions:
 - difficulty breathing, wheezing, chronic cough, allergies, asthma or other breathing conditions
 - a history of drug dependence, including alcohol dependence
 - skin rash (dermatitis)
 - skin irritation
 - a history of stomach ulcer.
 - liver disease.
 - kidney disease.
 - heart problems/failure, including swelling of ankles or feet.
 - thyroid problems or low blood pressure.
 - a head injury or intracranial pressure.
 - prostatic problems.
 - stomach problems or recent stomach surgery.

Tell your doctor if you take sedatives (medicines used to help you relax or sleep).

If you have not told your doctor about any of the above, tell him/her before you start taking Nurofen Plus.

Taking other medicines

Tell your pharmacist or doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with Nurofen Plus.

These include:

- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives.
- aspirin, salicylates or other NSAID medicines.
- warfarin or other medicines used to prevent blood clots.
- medicines that are used to treat high blood pressure including diuretics (fluid tablets)
- methotrexate.
- zidovudine.
- lithium
- mifepristone, quinolone antibiotics
- medicines used to relieve stomach cramps, prevent travel sickness and to treat Parkinson's disease.
- medicines used to treat diarrhoea (eg. kaolin, pectin, loperamide).
- metoclopramide, a medicine used to treat nausea and vomiting
- selective serotonin reuptake inhibitors (SSRIs), and monoamine oxidase inhibitors (MAOIs), medicines used to treat some types of depression
- quinidine, a medicine used to treat abnormal or irregular heart beat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- medicines such as cyclosporin, tacrolimus, prednisone, prednisolone and cortisone which reduce the activity of your immune system
- probenecid - medicines used to treat gout
- phenytoin - medicine used to treat epilepsy
- other opioid pain killers.

These medicines may be affected by Trust Ibuprofen Plus Codeine or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your pharmacist and doctor have more information on medicines to avoid or be careful with while taking Trust Ibuprofen Plus Codeine.

How to Take Trust Ibuprofen Plus Codeine

Follow all directions given to you by your pharmacist or doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your pharmacist or doctor for help.

How much to take

The usual dose of Trust Ibuprofen Plus Codeine is 2 tablets then, if necessary 1 or 2

tablets every 4 to 6 hours. **Do not take more than six tablets in 24 hours.**

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How to take it

Take Trust Ibuprofen Plus Codeine by mouth with fluid. It may also be taken with or immediately after food.

How long to take it

You should not take Trust Ibuprofen Plus Codeine for more than a few days.

If your symptoms persist, worsen or new symptoms develop, talk to your doctor.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (in Australia 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much Trust Ibuprofen Plus Codeine. Do this even if there are no signs of discomfort or poisoning.

If you take too much of this medicine you may experience nausea or upset stomach, vomiting and/or gastric irritation, drowsiness, dizziness and/or very slow, laboured breathing. You may also experience blurred vision, ringing in the ears, or rapid uncontrollable movements of the eyes. Excitability, convulsions and unconsciousness may be experienced in rare cases.

While You Are Using Trust Ibuprofen Plus Codeine

Things you must do

If you become pregnant while taking Trust Ibuprofen Plus Codeine tell your doctor immediately.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Trust Ibuprofen Plus Codeine.

Tell all of the doctors, dentists and pharmacists that are treating you that you are taking Trust Ibuprofen Plus Codeine.

If you are going to have surgery, tell your doctor you are taking Trust Ibuprofen Plus Codeine.

Talk to doctor if your symptoms do not improve.

Your doctor will assess your condition and decide if you should continue to take the medicine.

Things you must not do

Do not give Trust Ibuprofen Plus Codeine to anyone else, even if they have the same condition as you.

Do not use Trust Ibuprofen Plus Codeine to treat any other complaints unless your doctor tells you to.

Do not take more than the recommended dose unless your doctor tells you to.

Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.

Things to be careful of

Be careful driving or operating machinery until you know how Trust Ibuprofen Plus Codeine affects you.

Trust Ibuprofen Plus Codeine may cause dizziness, light-headedness or drowsiness in

some people. If this occurs, do not drive or operate machinery. If you drink alcohol, dizziness, light-headedness and/or drowsiness may be worse.

Do not take high doses of the medicine for long periods of time unless your doctor tells you to.

Products containing codeine should not be taken for prolonged periods. Codeine may be habit forming.

Side Effects

Check with your doctor as soon as possible if you have any problems while taking Trust Ibuprofen Plus Codeine, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Trust Ibuprofen Plus Codeine can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Do not be alarmed by this list of side effects. You may not experience any of them.

Ask your pharmacist or doctor to answer any questions you may have.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- stomach upset including nausea (feeling sick), vomiting.
- heartburn, indigestion.
- loss of appetite
- sleeplessness, nightmares
- change in mood for example depression, restlessness, irritability
- sore or dry mouth or tongue
- diarrhoea, pain in the stomach.
- dizziness, light-headedness, drowsiness.
- constipation.
- shallow breathing.
- cough suppression.
- headache.
- hearing disturbance.

These are the more common side effects of Trust Ibuprofen Plus Codeine and are usually mild and short lived.

Tell your doctor as soon as possible if you notice any of the following:

- shallow breathing or shortness of breath
- unusual or extreme mood swings
- dizziness, light-headedness
- flushing of the face
- fast heart beat
- severe pain or tenderness in the stomach
- eye problems such as blurred vision, sore red eyes, itching
- severe dizziness, spinning sensation
- severe or persistent headache
- tingling or numbness of the hands or feet
- difficulty hearing, deafness
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- signs of anaemia, such as tiredness, being short of breath, and looking pale

- a change in the colour of urine passed, blood in the urine
- a change in the amount or frequency of urine passed, burning feeling when passing urine
- yellowing of the skin and eyes, also called jaundice
- unusual weight gain, swelling of ankles or legs
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal

The above side effect may be serious and may require urgent medical attention.

Serious side effects are rare for low doses of this medicine and when used for a short period of time.

If any of the following happen, stop taking Trust Ibuprofen Plus Codeine and tell your doctor immediately or go to casualty at your nearest hospital:

- vomiting blood or material that looks like coffee grounds.
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea.
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.
- asthma, wheezing, shortness of breath, pain or tightness in the chest
- sudden or severe itching, skin rash, hives, skin peeling
- easy bruising

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your pharmacist or doctor if you notice anything that is making you feel unwell.

Some people may get other side effects while taking Trust Ibuprofen Plus Codeine. Tell your doctor or pharmacist if you notice anything else that worries you.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After Using Trust Ibuprofen Plus Codeine

Storage

Keep the tablets in the original pack until it is time to take the dose.

If you take them out they will not keep well.

Keep the tablets in a cool dry place where the temperature stays below 30°C.

Do not store Trust Ibuprofen Plus Codeine tablets or any other medicine in the bathroom or near a sink.

Do not leave the tablets in the car or on windowsills. Heat and dampness can destroy some medicines.

Keep the tablets where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

When you stop taking Trust Ibuprofen Plus Codeine or it has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

More Information

If you have any further questions or if you are not sure about anything relating to the use of Trust Ibuprofen Plus Codeine tablets, your doctor or pharmacist can best assist you.

Product Description

What it looks like

Trust Ibuprofen Plus Codeine tablet is white to off-white capsule-shaped, biconvex, film-coated tablet.

Ingredients

Trust Ibuprofen Plus Codeine contains 200mg Ibuprofen and 12.8mg Codeine phosphate hemihydrate as the active ingredients.

The other ingredients in Trust Ibuprofen Plus Codeine are:

- starch – pregelatinised maize
- cellulose microcrystalline
- croscarmellose sodium
- silica colloidal anhydrous
- water purified
- opadry white colouring

Trust Ibuprofen Plus Codeine tablets do not contain gluten, lactose or preservatives.

Presentation:

Trust Ibuprofen Plus Codeine tablets are available in Australia in blister packs of 10, 12, 15, 18, 20, 24, and 30 tablets*.

*Not all pack sizes are marketed in Australia.

Distributor:

Pharmacor Pty Ltd
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821 Pacific Highway,
Chatswood NSW 2067
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